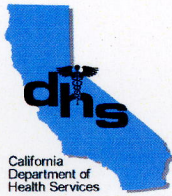


State of California—Health and Human Services Agency
Department of Health Services



SANDRA SHEWRY
Director



ARNOLD SCHWARZENEGGER
Governor

June 6, 2005

TO: ALL CLINICAL LABORATORIES

SUBJECT: CLINICAL LABORATORIES OVERSIGHT PROGRAM

In order to ensure that the integrity of California's laboratory standards be sustained and to ensure that laboratories be maintained and operated without injury to the public, the California Department of Health Services is announcing its intention to strengthen the enforcement of its oversight of clinical laboratories.

For a number of years the Department has been inconsistent in its collection of fees from several laboratory classifications (laboratories newly regulated under state law passed in 1995), which has affected its ability to oversee clinical laboratories and ensure that they are complying with state laws regulating clinical laboratories and clinical laboratory personnel.

The Department remains committed to petitioning the federal Centers for Medicare and Medicaid Services (CMS) for Clinical Laboratory Improvement Amendments (CLIA) exemption for California in the interest of eliminating duplicate oversight of clinical laboratories in the state. As preparations for an application to CMS for CLIA exemption proceed, the Department will be moving forward with ensuring full compliance with the state law.

- The Department will enforce the requirement that all laboratories in California pay the fees required under state law. New laboratories will be required to submit the appropriate licensure fees with their application prior to issuance of a license/registration.
- The Department will notify previously certified laboratories by the day and month of expiration shown on their federal CLIA certificate. If you have not received your renewal and fee amount by the date your license or registration expires, please contact the Department.

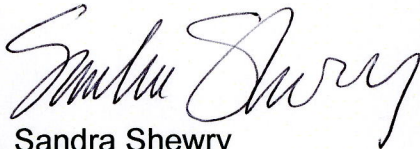
All Clinical Laboratories

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- Clinical laboratories whose CLIA certificates served as their state registration or license as of December 31, 1995, and have been unchanged since that date (Title 17, California Code of Regulations (CCR), Section 1039.1) will continue to be exempted from paying fees.
- The Department intends to promulgate regulations in the next year to remove the exemption provision described in the bullet above (Title 17, CCR, Section 1039.1) thereby requiring licensure and/or registration of all clinical laboratories located in California or receiving biological specimens originating in California.
- The Department will actively seek exemption from CLIA program requirements when all laboratories in California are licensed or registered. However, legislation may be required to make California law consistent with federal law.

The Department appreciates the cooperation and assistance of the state's clinical laboratories during this important transition. The Department has updated services available on-line to help facilitate the licensing and registration processes <http://www.dhs.ca.gov/ps/ls/LFSB/default.htm>. If you should have any questions concerning the clinical laboratory oversight program, please contact the Laboratory Field Services Branch at (510) 873-6361, (510) 873-6405, or (510) 873-6360.



Sandra Shewry
Director